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In the Supreme Court of the United States

OCTOBER TERM 1976

FIRST NATIONAL BANK IN ALBUQUERQUE
as Guardian for and on behalf of
DOROTHY JEAN HUCKLEBY, CHARLES AMOS HUCKLEBY, ERNESTINE HUCKLEBY and MICHAEL HUCKLEBY; DOROTHY JEAN HUCKLEBY; LOIS HUCKLEBY and ERNEST HUCKLEBY,

Petitioners,

vs.

UNITED STATES OF AMERICA

Respondent.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE TENTH CIRCUIT

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Respondent.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE TENTH CIRCUIT

Petitioners respectfully pray that a writ of certiorari be issued to review the judgment and opinion of the United States Court of Appeals entered in this action on March 24, 1977.

OPINIONS BELOW

The opinion of the Court of Appeals, 552 F.2d 370 (1977), appears in the appendix hereto at App. 1. The unreported opinion of the District Court appears in the appendix hereto at App. 17.

JURISDICTION

The judgment of the Court of Appeals for the Tenth Circuit was entered March 24, 1977. This court has jurisdiction under 28 U.S.C.A. § 1254(1).

QUESTIONS PRESENTED

The questions presented in this case are:

1. Whether the decisions of government personnel regarding the precautionary language for the labeling of economic poisons involve (a) policy judgment and choice which is subject to the discretionary function exception to liability of the United States under the Federal Tort Claims Act, or (b) evaluation guided by statutory and regulatory criteria, which does not involve policy judgment and choice.

2. Whether acts and omissions of government personnel in failing to marshal and submit to a decision-maker the facts necessary to a decision on suspension or cancellation of the registration of an unreasonably dangerous product are subject to the discretionary function exception.

STATUTORY AND REGULATORY PROVISIONS INVOLVED

The statutory and regulatory provisions involved in this case, which appear in full text in the appendix hereto at App. 34, are 7 U.S.C.A. §§ 135, 135a, 135b (1964), 28 U.S.C.A. §§ 2674, 2680 (1965), 40 C.F.R. §§ 162.9, 162.10, 162.14, 162.105, 162.116 (1974). At all times material to this case, the Department of Agriculture administered the Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C.A. §§ 135 *et seq.* (1964). Administration of the Act was transferred to the Environmental Protection Agency by Reorganization Plan No. 3 of 1970, § 2(a)(8)(i), effective December 2, 1970, 35 F.R. 15623, 84 Stat. 2086. Also, at all times material to this case, the regulations were codified at 7 C.F.R. 162.1 *et seq.*

STATEMENT OF THE CASE

This is an action filed by plantiffs in the United States District Court for the District of New Mexico for the recovery of personal injury damages. The plaintiffs claimed that four children of the Huckleby family sustained mercury poisoning as a proximate result of the defendant's negligence in failing to exercise due care to require of the registrants of alkyl mercury fungicide formulations (a) adequate and non-misleading warnings, (b) adequate directions and instructions and/or (c) removal from the market of mercury compounds which were used as seed treatments.

The complaint was filed pursuant to the Federal Tort Claims Act on September 18, 1972. Trial was had in the District Court and judgment entered on January 29, 1975. The judgment dismissing plaintiffs' complaint and cause of action was appealed, and the Court of Appeals for the Tenth Circuit affirmed the District Court on March 24, 1977.

In August, 1969, Ernest Huckleby and other Alamogordo hog-raisers obtained grain from a seed company in Clovis, New Mexico. On the two separate occasions that Mr. Huckleby went to the seed company, feed grain was purchased and then employees of the seed company gave to Mr. Huckleby and the men with him old grain which was partially bagged and stored in sheds. The employees also helped the men load the old grain. The bags of old grain contained minute amounts of fungicide treated grains which had been swept up from the floor in the seed treatment processing area at the seed company. These sweepings were put in bags with other grain screenings and refuse and placed in the sheds.

The fungicide used in the application process was Panogen 15, a liquid alkyl mercury compound, which was designed to prevent the attack of fungus on seeds and growing plants. In the treatment process, grains would be funneled into a rotating drum where they would be sprayed with the liquid Panogen. The grains would then be bagged and sold as seed. "Sweepings"

consisted of treated grains which spilled to the floor during the treating process. "Screenings" consisted of untreated grains and chaff separated from select grain prior to treatment. The hog-raisers eventually fed much of the sweepings and screenings to their hogs.

In the first week of October, Mr. Huckleby slaughtered one of his hogs for family consumption and, after the meat had been prepared by a local butcher, the family began eating it at least once each day until the end of November.

In early December, the first of the Huckleby children became ill. By early January two more children were ill, and by this time government investigators had been called in to determine the source of the poisoning. In March, 1970, Mrs. Huckleby delivered a baby boy who also was found to have contracted organic mercury poisoning during gestation.

As the hog ate small amounts of the grain on a daily basis, the mercury level built up in its body and remained there at the time it was slaughtered. When the Huckleby family began eating the hog meat, the level of alkyl mercury began building up in their bodies. Since alkyl mercury poisoning normally affects only the young, the adult members of the Huckleby family escaped damage. Alkyl mercury poisoning does irreversible damage to the central nervous system and in the case of the Huckleby chilren, it has affected speech, locomotion and physical coordination. It has also caused blindness or otherwise impaired vision.

The Federal Insecticide, Fungicide and Rodenticide Act of 1947, 7 U.S.C.A. §§135 *et seq.* (1964), hereafter referred to as FIFRA, provided control by the federal government over certain aspects of the manufacturing and distribution of economic poisons. The Department of Agriculture, through the Pesticides Regulations Division, was the agency responsible for effectuating the requirements of the Act. No pesticide could be shipped in interstate commerce unless it was registered with the Pesticides Regulation Division, sometimes hereafter

referred to as PRD. In order for a product to be registered, the manufacturer had to submit an application for registration, together with copies of a label it proposed to use on the product. The Act also provided for a re-registration application every five years.

The work of the PRD involved two basic aspects to the review of a manufacturer's application for registration. The efficacy review was a check to see if the chemical, itself, performed as claimed by the manufacturer in the uses for which it was designed. FIFRA required that the PRD not register a product if the proposed claims for it were not fulfilled. In addition to evaluation of the chemical, itself, efficacy review involved a check of the proposed label to see if it contained correct representations and advice concerning the methods and rates of usage and chemical content.

Safety review involved a check of the precautionary language that would be required in a label. For the purpose of considering precautionary label language, FIFRA required PRD to meet certain criteria set forth in sections 135 through 135k of the Act. 7 U.S.C.A. § 135b(b), (c) (1964).

Section 135a of the Act, with which labeling was required to comply, provides that it is unlawful to distribute any misbranded economic poison. 7 U.S.C.A. § 135a(5) (1964). Determination of a label's compliance with the "misbranded" standard is based on the following criteria set forth in the statutes and regulations:

(1) False or misleading statement. 7 U.S.C.A. § 135(z)(1) (1964).

(2) Directions for use which are necessary, and if complied with adequate for the protection of the public. *Id.* § 135(z)(2)(c).

(3) Warning or caution statement which may be necessary, and if complied with adequate to prevent injury. *Id.* § 135(z)(2)(d).

(4) Prominent and conspicuous statements. *Id.* § 135(z)(2)(f).

(5) Terms likely to be read and understood. *Id.*

(6) Product injurious to man or animal when used in accordance with commonly recognized practice. *Id.* § 135(z)(2)(g).

(7) A true statement used in such a way as to give a false or misleading impression to the purchaser. 7 C.F.R. § 162.14(a)(9).

(8) Concise and easily understood warnings as to the hazards associated with use. 7 C.F.R. § 162.116(c)(1).

(9) Concise and easily understood instructions to be followed to insure adequate protection. *Id.*

The Safety Section of the Pesticides Regulation Division worked on the precautionary language that went on the labels. (Tr. Vol. XVIII 820). The statute, regulations and policies decided upon by the agency were the guidelines that were looked to by the personnel conducting review of labels. (Tr. Vol. XVIII 756-57.) The scientists who worked on evaluation of label language were expected to stay abreast of developments in their particular fields. Consideration of the labels was definitely not made in a vacuum. (Tr. Vol. XVIII 822, 975.) The manufacturer would be advised of any defects in the label and corrections to be made so that another label could be submitted with the product.

Panogen was first registered in 1953. In addition to an initial label language evaluation, the Pesticides Regulation Division was required to review the product and its labeling every five years. This was called the re-registration process. Dr. Cueto, a pharmacologist who did work in label language evaluation, testified at trial that re-registration involved going through the

label step by step to determine if anything needed improvement or wasn't consistent with more recent thinking. He stated, "See, we're dealing with evolutionary-type of information that could develop, so it's not a static thing that we're dealing with." (Tr. Vol. XVIII 934.) The reviewer would consider the uses of the product so that a determination could be made concerning the precautionary statements that would be suitable for those uses. (Tr. Vol. XVIII 937.) The precautionary statement would hopefully minimize exposure to the product and thereby reduce the hazard associated with its use. (Tr. Vol. XVIII 938-39.) Dr. Cueto testified that the warning and directions were designed to inform the user about the nature of a product's hazard and how to avoid it:

> Q. But as far as you were concerned, and a man in your business about human safety, there were also those two concepts: warning, which would be adequate to bring home to the user the nature and extent of the danger, and secondly, directions for how he uses the product so he won't get into trouble because of the danger?
>
> A. Yes, the main thrust of actual precautionary statements – and again, this is a matter of custom; it's a matter of evolution – has been to indicate how or where one should prevent exposure; should one prevent exposure from inhalation? Should one prevent exposure dermally? So that one doesn't tell a person how to hold a bucket or how to hold it away from him, but tells him not to get it on his hands."

(Tr. Vol. XVIII 952.)

Dr. Harry Hays, who was the Director of the Pesticides Regulation Division from 1966 to 1970, testified in direct examination concerning the risk-benefit ratio in agriculture. He

stated, "The benefits to be derived in providing food and fiber, very often far outweigh the risk that one might take in the use of that chemical." (Tr. Vol. XVI 636.) He gave use of DDT as an example:

> "The DDT was, I think, one that probably exemplifies this very much. If there was any risk, it was, in my opinion, a very small risk. The benefits to be derived were tremendous. The benefits, not only in agriculture, the benefits that were derived during the war when millions of people, of our soldiers, at least, who benefited from the use of DDT. We probably couldn't have fought the war without it. And yet, we now seem to say that the risk is too great, because it is ubiquitous in nature; it is pervasive; it is persistent, and it does persist in the environment, and here we now have to try to equate the concept of risk-benefit. Sometimes we think we are justified taking a certain degree of risk."

(Tr. Vol. XVI 637.) With regard to the registration of economic poisons, the patterns of use of a given chemical would be considered in light of the risk-benefit to the public at large. (Tr. Vol. XVI 637-38.)

Dr. Hays' testimony makes it clear that the risk-benefit concept would be utilized in deciding whether a product should be marketed in interstate commerce. But, as compared with marketing of a product, this risk-benefit concept played no part, whatsoever, in the evaluation and choice of precautionary label language as the following dialogue between Dr. Hays and counsel for plaintiff's shows:

> "Q. When considering the adequacy of the warning and the directions for use on the label, no punches were pulled when it came to telling about the nature and extent of the danger, in order to enhance the saleability of the product?
>
> A. No, that's right, I agree with you.

> Q. And when you're talking about risk and benefit ratio, you – you're not talking, at all, about considering labels for adequacy as to warning and directions for use, *because you would give the best warning and the most adequate directions called for, regardless of the toxicity or this risk-benefit ratio?*
>
> A. *That's right.*"

(Tr. Vol. XVIII 825-26.) (Emphasis added).

Panogen was first registered by PRD in 1953. Throughout the history of its registration, the uses for which it was designed, the containers in which it was packaged, and the labeling that went with the product were subject to a number of changes. Material to this case, however, the liquid Panogen that was sold to and used by the seed company came in 54 gallon barrels. A paper label was placed on each barrel. The right panel of the label contained language relative to the proposed uses of the product, the recommended dosages and the manufacturer's disclaimer of warranty. This efficacy portion of the label and efficacy review was not complained of by plaintiff and is not relevant to the issues in this review.

In addition, the middle and left panels of the label contained general information and precautionary language. As specifically required by statute, there was included a skull and cross bones, the word "poison" and an antidote statement. 7 U.S.C.A. § 135a(3) (1964).

It is with regard to omitted "necessary and adequate if complied with" warnings and directions that plaintiffs claim the PRD failed in its duty as required by statute.

In order to satisfy the duty of care in giving an adequate warning of a product's dangers, one must not only provide indication of danger but also provide understandable information that is reasonably calculated to bring home to the reason-

able person the nature and extent of the danger. *Spruill v Boyle-Midway, Inc.*, 308 F.2d 79 (4th Cir. 1962). As contemplated by the Tort Claims Act, the United States shall be liable in the same manner and to the same extent as a private individual under like circumstances. 28 U.S.C.A. § 2674 (1965). As plaintiffs had claimed at trial and as found by the District Court in its decision, the defendant did have a duty to the general public, including the plaintiffs, in carrying out the requirements of FIFRA. (Tr. Vol. I 58, 61.)

At trial, plaintiffs offered evidence to show that PRD personnel involved in the safety review of labels for alkyl mercury products knew that: there was no therapy for chronic mercury poisoning, there were food chain poisoning effects, alkyl mercuries caused delayed and cumulative poisoning effects, there were sweeping waste contamination hazards, there were risks attending storage of treated seed, minute quantities of alkyl mercury produced poisoning hazards, and there was casual use of treated grain as feed. (Tr. Vol. XIV 212-485.) And, representatives of the PRD who testified at trial admitted that they knew of these dangers and knew of them prior to the Huckleby incident. (Tr. Vol. XVIII 767-793, 955-956, 961-962.)

It was plaintiff's claim, with regard to the defective labeling, that the only protection available to hog-raisers using grain screening and sweeping products was the caution of the seed company processors, who, faced with inadequate warnings and directions, were incapable of recognizing harmless-looking non-commercial treated grain for the dangerous agent that it was. Without additional warning and direction, the processors did not have the knowledge to invoke their caution on behalf of the hog-raisers to whom they distributed the screenings and sweepings which bore some remnants of treated seed.

As an additional, and alternative, claim to the negligence of the PRD in the labeling activity, plaintiffs claimed that the PRD personnel in charge of safety review negligently failed to marshal and submit to the decision-maker the knowledge available

to them on the nature and extent of Panogen dangers which would have resulted in removal of the product from the market.

Prior to the Huckleby incident, a policy choice was never made on the question of suspension or cancellation of the Panogen registration. The Secretary of Agriculture was empowered by FIFRA to suspend or cancel an economic poison not complying with the Act. 7 U.S.C.A. § 135b(c). By regulation, cancellation could result at the time of re-registration if the product or labeling failed to comply with the Act. 7 C.F.R. § 162.10(j). And, by agency policy, cancellation had to be considered, during the course of product's registration, if use experience indicated a hazard to human or animal health. (Tr. Vol. XV 459, Plaintiffs' Ex. 97.)

The Court of Appeals, in affirming the decision of the District Court, concluded that the activity of the PRD in the evaluation of precautionary labeling, in addition to the specific statements required by statute, and in the evaluation of a product and its labeling for the purpose of possible cancellation, was involved in the making of policy judgments or choices and therefore immune from suit pursuant to the discretionary function clause of the Tort Claims Act. 28 U.S.C.A. § 2680(a) (1965).

It is plaintiffs' position in this case that the Court of Appeals and the District Court erroneously applied the law to the question of the exercise of discretionary function by PRD personnel in the safety review of labeling and possible cancellation.

REASONS FOR GRANTING THE WRIT

IT IS UNSETTLED WHETHER THE SAFETY EVALUATION OF PRODUCTS REGULATED BY GOVERNMENT IS SUBJECT TO THE DISCRETIONARY FUNCTION EXCEPTION TO THE LIABILITY OF THE UNTED STATES UNDER THE FEDERAL TORT CLAIMS ACT.

This court has not directly addressed itself to the increasingly important federal law question of whether product safety regulation, involving mainly scientific evaluation, is subject to the discretionary function exception to the liability contemplated of the United States in the Federal Tort Claims Act. Underlying the importance of this question is the pervasive involvement of the federal government in regulating products and services of the private sector, and the expectations and reliance generated in the individual citizen that government is carefully managing such activity.

The evidence in this case shows that scientists, primarily pharmacologists, evaluated warnings and directions that would be included in the safety labels of economic poisons. The statutory provisions and the regulations and policies of the Pesticides Regulation Division required that the evaluator identify and place on a label the necessary and adequate warnings and directions applicable to the economic poison. Safety evaluation, then, basically involved decisions of whether the labeling contained necessary and adequate warnings and directions. The decision making process was based on evolving information of the product's dangers and its uses.

Safety review personnel of the Pesticides Regulation Division admitted that they knew of the seven dangers that plaintiffs claim were not covered in the label and that they knew of these dangers prior to the Huckleby incident. The evidence also

shows, through the testimony of the Director of the Pesticides Regulation Division, that risk benefit analysis, utilized by the agency when making ultimate decisions on registration and cancellation of economic poisons, was not involved in considering the necessity and adequacy of label warnings and directions.

Both the District Court and the Court of Appeals concluded that decisions of what were necessary and adequate warnings and directions (and the process of marshalling evidence for the consideration of cancellation) involved scientific as well as *public policy* considerations.

In the opinion of both the District Court and the Court of Appeals the involvement of public policy considerations required the conclusion that the discretionary function exception applied to the activity of safety label evaluation. Neither court, however, was able to articulate any conceptual or factual reason to explain why or how the label evaluators necessarily used *public policy* judgment in making the decisions of what were necessary and adequate warnings and directions.

The extent to which the decisions of the District Court and Court of Appeals and the decisions of other federal courts have been unable to articulate precise and concise guidelines for consideration of *discretionary function*, and the vacuum that the federal courts have been attempting to fill since this court's decisions in the 1950's, demonstrates the need for this court to settle the questions presented.

A. THE DECISION OF THE COURT OF APPEALS CONFLICTS WITH THE CONCEPT OF DICRETIONARY FUNCTION AS ARTICULATED BY THIS COURT.

In *Dalehite v. United States*, 346 U.S. 15 (1953), this court concluded that a government program of manufacture and shipment of potentially explosive fertilizer was subject to the discretionary function exception of the Federal Tort Claims Act.

The program was carried out in accordance with a government plan which, among other things, specifically required labeling of fertilizer bags in accordance with government regulations. The labeling was carried out in strict accordance with these regulations, and probably any deviation would have been forbidden. On the question of what decision making would be classified as the exercise of discretionary function, this court stated:

> "It is unnecessary to define, apart from this case, precisely where discretion ends. It is enough to hold, as we do, that the 'discretionary function or duty' that cannot form a basis for suit under the Tort Claims Act includes more than the initiation of programs and activities. It also includes determinations made by executives or administrators in establishing plans, specifications or schedules of operations. Where there is room for policy judgment and decision there is discretion.
>
> * * * *
>
> The acts found to have been negligence were thus performed under the direction of a plan developed at a high level under a direct delegation of plan-making authority from the apex of the Executive Department.
>
> * * * *
>
> In short, the alleged 'negligence' does not subject the government to liability. The decisions held actionable were all responsibly made at a planning rather than operational level and involved considerations more or less important to the practicability of the Government's fertilizer program."

Dalehite v United States, supra, 346 U.S. at 35-36, 39-40, 42.

In *Indian Towing Co. v. United States*, 350 U.S. 61 (1955) the government claimed that lighthouse activity was a uniquely government function for which, by reference to the implica-

tions of the discretionary function clause and 28 U.S.C.A. § 2764 (1965) (the United States to be liable like a private individual under like circumstances), it could not be held liable for failure of a lighthouse light. It was stated in the opinion that all government activity is uniquely governmental because performed by government and, yet, it would be difficult to conceive of a government activity that could not be privately performed. Concerning the discretionary aspect of the lighthouse activity, this court stated:

> "The Coast Guard need not undertake the lighthouse service. But once it exercised its discretion to operate a light on Chandeleur Island and engendered reliance on the guidance afforded by the light, it was obligated to use due care to make certain that the light was kept in good working order; and, if the light did become extinguished, then the Coast Guard was further obligated to use due care to discover this fact and to repair the light or give warning that it was not functioning. If the Coast Guard failed in its duty and damage was thereby caused to petitioners, the United States is liable under the Tort Claims Act."

In *Rayonier, Inc. v. United States*, 352 U.S. 315 (1957), this court, again, rejected the "uniquely governmental"argument to hold that the United States could be held liable for fire-fighting activity if private persons under like circumstances would be liable under the local law.

In *Hatahley v. United States*, 351 U.S. 173 (1956), this court held that acts of the Department of Interior's Range Manager in prosecuting a campaign to impound and destroy horses grazed on public lands by the Navajo were not done in the exercise of discretion under the guidance of the Taylor Grazing Act. Although the decision does not state the reason for holding that the discretionary function exception did not apply, the case facts show that the federal agents did not comply with regulatory directives governing their activities.

The most simple mental exercise or judgment might be said to involve the use of discretion. At the crux of the issue of governmental immunity is the special policy-making dimension contemplated by the statutory grant of immunity for the exercise of *governmental discretion.*

The discretion exercised by the Coast Guard personnel for which the government was liable in *Indian Towing,* in deciding the means and methods by which the lighthouse would be inspected, maintained and repaired, or by which warning would be given of inoperative condition, was a mental exercise or judgment equal in character to that of determining the need for and content of warnings and directions to go on the labels of eco-economic poisons.

In *Dalehite,* the wording actually used on fertilizer labels was directed by regulation. *Any inadequacy of language was a result of an error or mistake made in promulgating the regulation, a protected policy judgment decision.* On the other hand, the statutory and regulatory "plan" determined by Congress and agency executives under FIFRA called for the evaluator's choice of label language to accomplish the objective of communicating necessary and adequate warnings and directions to users of economic poisons. *Any inadequacy of language was a result of the evaluator's error or mistake in failing to comply with the duty to warn and direct against the nature and extent of a product's dangers.*

The evaluator's judgment of the need for and content of label language cannot be considered the exercise of a risk-benefit judgment. Nor can any decision concerning the content of label language be said to involve the practicability or feasibility of government's involvement in regulating the safety aspects of economic poisons.

The mandate that necessary and adequate warnings and directions should be included in the label of an economic poison is a policy requirement of government that is no different from the common law duty of care to provide indication

of danger and understandable information calculated to bring home to the reasonable person the nature and extent of the product's danger.

The concept of discretionary function expressed in the decisions of this court requires the conclusion that no protected discretionary function would be involved in non-compliance with the policy directives that necessary and adequate warnings and directions should be included in safety labels.

The conclusion of the Court of Appeals that discretionary function, and the making of policy judgments, was in some way involved in the choice of label language is in conflict with the previous decisions of this court.

B. THE DECISION OF THE COURT OF APPEALS IS IN CONFLICT WITH DECISIONS OF OTHER COURTS OF APPEALS ON THE QUESTION OF THE APPLICABILITY OF DISCRETIONARY FUNCTION.

Since the inception of the Tort Claims Act, courts have considered application of *discretionary function* with a variety of theory and logic in an effort to give it true meaning. If the decision in question is made in execution of an existing policy or plan which guides the decision, it is more likely to be considered as an unprotected judgment, whereas if the decision initiates or creates a policy or plan, it is more likely to be considered as protected. *Seaboard Coast Line Railroad Company v. United States,* 473 F.2d 714 (5th Cir. 1973); *Hendry v. United States,* 418 F. 2d 774 (2nd Cir. 1969); *Oman v. United States,* 179 F.2d 738 (10th Cir. 1949).

The practical test of *discretionary function* that is used in the decisions is to question whether the complained of activity involved the making of a public policy judgment or choice, which would be a protected function, or whether it involved the implementation or execution of public policy or plans.

which would be an unprotected function. This is the test acknowledged in the District Court's decision. (*See*, Tr. Vol. I 59, 61.)

In *Griffin v. United States*, 500 F. 2d 1059 (3rd Cir. 1974), the plaintiffs contended that the Public Health Service negligently approved polio vaccine for release to the public. The Division of Biological Standards, of the Public Health Serivce, was directed by regulation to evaluate a manufacturer's polio vaccine for neurovirulence by reference to five enumerated criteria. The court expressly rejected the government's argument that Congress intended, by the discretionary function exception, to exclude all claims arising from regulatory activity. The opinion analyzed discretionary function in light of the principle of public policy, which the court attributed to this court's decision in *Dalehite*, and referred to other federal cases holding that the discretionary function exception did not apply to decisions of government not involving policy judgments as to the public interest. The court believed that the decisions in *Dalehite* involved considerations of public policy which called for balancing such factors as *cost of government programs against potential benefit*.

The Court of Appeals concluded that evaluation of the criteria for neurovirulence did not involve policy making, decision or judgment:

> "We acknowledge that under DBS' construction of the regulation, the implementation called for a judgmental determination as to the degree to which each of the enumerated criteria indicated neurovirulence in monkeys. The judgment, however, was that of a professional measuring neurovirulence. It was not that of a policy-maker promulgating regulations by balancing competing policy considerations in determining the public interest. Neither was it a policy planning decision for a determination of the feasibility or practicability of a government program. At issue was a scientific, but not policy-making, determinaton as to whether each of the criteria listed in the regulation was met and the extent to which each such

factor accurately indicated neurovirulence. DBS' responsibility was limited to merely executing the policy judgments of the Surgeon General. It had no authority to formulate new policy in the immunization program.

Where the conduct of Government employees in implementing agency regulations requires only performance of scientific evaulation and not the formulation of policy, we do not believe that the conduct is immunized from judicial review as a 'discretionary function.' As Judge Waterman of the Second Circuit has stated:

> 'The fact that judgments of government officials occur in areas requiring professional expert evaluation does not necessarily remove those judgments from the examination of courts by classifying them as discretionary functions under the Act.'

Hendry v. United States, 418 F. 2d 774, 783 (2nd Cir. 1969)."

Griffin v United States, supra, 500 F.2d at 1066.

The function of the Pesticides Regulation Division, in this case, was not different in substance from the function of the Division of Biological Standards in *Griffin*. As the product was subjected to safety evaluation in *Griffin*, the label, here, was subjected to safety evaluation. The label would either be accepted or rejected after evaluation of the misbranded criteria established by statute and regulation. The function of scientific evaluation in *Griffin* of "lesions charcteristic of polio virus infection", "severity of lesions" and "degree of dissemination of lesions" cannot be different in substance from the evaluation in this case of "directions for use which are necessary" and "warning or caution statement which may be necessary, and if complied with, adequate".

The Court of Appeals, in this case, agreed with the reasoning and result in *Griffin* but believed that the two cases were different because scientific measurement by the Public Health

Service personnel was done by reference to specific standards whereas, in this case, it was done in "general terms" for the protection of public safety. If the regulation in *Griffin* did not contemplate the exercise of policy judgment or decision by government personnel when involved in the function of evaluating the criteria, it is difficult to explain how the similar statutory and regulatory directives in this case would contemplate the making of policy judgments or choices. To this extent, the decision of the Court of Appeals is in conflict with *Griffin*.

The criteria for fulfilling the duty of giving necessary and adequate warnings and directions are well established in the common law. In disclosing the nature and extent of the danger, there must be specified any harmful consequence which a reasonably foreseeable user would not understand from a general warning of the product's danger or from a simple directive to use or not to use the product for a certain purpose or in a certain way.

Cases, which are in conflict with the decision of the Court of Appeals, have distinguished between the protected discretionary function in adopting a government plan or program and the unprotected function, which may involve discretion, in carrying out that plan or program. It has been held to be protected function to undertake services of rescue[1] or wrecked-ship marking[2], but not protected function to conduct those operations negligently. Admitting a patient to a hospital was protected, but treating or managing the patient negligently was not.[3] The decision to establish a post office at a particular location was protected but a failure to install handrails was

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1. *United States v Lawter*, 219 F.2d 559 (5th Cir. 1955).
United States v Stone DeVane, 306 F.2d 182 (5th Cir. 1962).

2. *Somerset Seafood Co. v. United States*, 193 F.2d 631 (4th Cir. 1951).

3. *White v United States*, 317 F.2d 13 (4th Cir. 1963).
United States v Gray, 199 F. 2d 239 (10th Cir. 1952).
Costley v United States, 181 F.2d 723 (5th Cir. 1950).

not.[4] Establishing control towers at airports and undertaking a program of air traffic separation was protected but negligent conduct in carrying out those functions was not.[5] The decision to reactivate an airbase was protected, but negligent construction of a drainage and disposal system, in the course of the reactivation construction, was not.[6] And, the Second Circuit Court has hypothesized that an engineer's determination of whether a particular program of production is desirable or not would be protected, but that same engineer's decisions as to engineering efficiency and safety would not be protected.[7]

The commander of the Strategic Air Command exercised discretionary function in ordering supersonic training missions, but an Air Force regulatory directive calling for "maximum protection for civilian communities" left no room for the exercise of discretionary function in deciding the means to fulfill the directive.[8]

A Corps of Engineers safety manual governing contractors required the use of safety protection devices on construction equipment. The decision of the government's resident engineer that bulldozer canopies were not appropriate for a project was based on general standards of safety and not the exercise of discretionary function.[9] Selection of an aircraft by the Secretary of the Air Force, and his staff, constituted the exercise of discretionary function but acceptance of a defective ejection

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4. *American Exchange Bank of Madison, Wis. v United States*, 257 F.2d 938 (7th Cir. 1958).

5. *United States (Eastern Airlines) v. Union Trust Co.*, 221 F.2d 62 (D.C. Cir. 1955); *aff'd*, 350 U.S. 907 (1955).

6. *United States v. Hunsucker*, 314 F.2d 98 (9th Cir. 1962).

7. *Hendry v. United States*, 418 F. 2d 774, 783 (2nd Cir. 1969).

8. *Nelms v. Laird*, 442 F.2d 1163 (4th Cir. 1971), *rev'd on other grounds*, 406 U.S. 797 (1972).

9. *United States v. DeCamp*, 478 F.2d 1188 (9th Cir. 1973).

seat system was not the exercise of discretionary function.[10] An Air Force Base Civil Engineer was not exercising a protected discretionary function in choosing not to install warning devices, barriers, speed control devices or crosswalks on a street located on the base.[11]

Respectfully,
William G. Gilstrap and
Richard E. Ransom
Attorneys for Petitioners

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10. *Moyer v. Martin Marietta Corp.*, 481 F.2d 585 (5th Cir. 1973).

11. *Driscoll v. United States*, 525 F.2d 136 (9th Cir. 1975).

APPENDIX

APPENDIX A

UNITED STATES COURT OF APPEALS
TENTH CIRCUIT

FIRST NATIONAL BANK IN ALBUQUERQUE as Guardian for and on behalf of DOROTHY JEAN HUCKLEBY, CHARLES AMOS HUCKLEBY, ERNESTINE HUCKLEBY and MICHAEL HUCKLEBY; DOROTHY JEAN HUCKLEBY; LOIS HUCKLEBY and ERNEST HUCKLEBY,	)
Plaintiffs-Appellants,	) No. 75-1301
v.	)
UNITED STATES OF AMERICA,	)
Defendant-Appellee.	)

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW MEXICO
(D. C. No. 9705)

William G. Gilstrap (Smith, Ransom & Gilstrap, Albuquerque, New Mexico, on the brief) for Plaintiffs-Appellants

William R. Hughes, Jr., Assistant United States Attorney (Victor R. Ortega, United States Attorney, Albuquerque, New Mexico, on the brief) for Defendant-Appellee

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Before HOLLOWAY, BARRETT and DOYLE, Circuit Judges

HOLLOWAY, Circuit Judge

This tragic case arose from the mercury poisoning of four children of a New Mexico Family. The source of the poison was meat from a hog which had been fed seed treated with a mercury fungicide. The plaintiffs appeal from a judgment dismissing their suit brought under the Federal Tort Claims Act, 28 U.S.C.A. §§ 1346(b), 2671 *et seq.*, for alleged negligence on the part of Government employees in the registration for interstate sale and approval of the labeling of the fungicide pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C.A. § 135 *et seq.*

The basic facts are not in dispute. Mr. Ernest Huckleby raised hogs as a sideline to his regular work as a janitor in the public schools of Alamogordo, New Mexico. In 1969, he and other local hog-raisers bought grain from the Golden West Seed Company in Clovis to be used as feed for their hogs. They were also given a large amount of "waste" grain which had been partially bagged and stored in a shed on the premises of Golden West. The waste grain included some seeds, pink in color, which had been treated with a mercury fungicide, Panogen 15, to protect the seed before it was planted.

The fungicide was manufactured by Morton Chemical Company, whose name was changed to Nor-Am Agricultural Products, Inc., before this litigation began. Panogen 15 was registered with, and its labeling was approved by, the Pesticides Regulation Division (PRD) of the Department of Agriculture pursuant to the provisions of FIFRA.

Some of the treated grain was mixed with garbage and fed daily to the family's hogs. One of the hogs was slaughtered in the fall of 1969 and the family began eating the meat daily. In early December the first of the Huckleby children became ill; by early January, two more children were similarly stricken, and a fourth was ultimately afflicted.[1] By this time, state and federal health authorities had been called in to determine whether an epidemic might be starting.

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[1] In March, 1970, Mrs. Lois Huckleby delivered a baby boy who had contracted organic mercury poisoning during gestation. The alkyl mercury contained in the pork eaten by Mrs. Huckleby during pregnancy had crossed the placenta and entered the system of the fetus.

In mid-January, after an investigation by these authorities, it was determined that the Huckleby children were suffering from organic mercury[2] poisoning as a result of their eating the meat from the hog which had been fed the grain treated with Panogen 15.[3] Thus a "food-chain" poisoning was involved.

Alkyl mercury poisoning does irreversible damage to the central nervous system. It affects sight, speech, locomotion and the ability to grasp objects or otherwise use one's hands properly. The Huckleby children suffered severe permanent injuries as a result of the poisoning,[4] as the district court found.

After an administrative claim was denied, plaintiffs brought this suit under the Federal Tort Claims Act.[5] Their main

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[2] The specific poisonous substance involved was a compound in the alkyl mercury group, *i.e.*, a methylmercury compound called Cyano-(methylmercuri)guanidine or Methylmercury dicyandiamide.

[3] Alkyl mercury is a highly toxic substance. Once ingested, it moves rapidly through the body and is absorbed, rather than passed off, by the body. As the hog ate the treated grain every day, the mercury level in its body increased and remained there at the time when the hog was slaughtered. When the Hucklebys began eating the meat from the hog, the level of alkyl mercury in their bodies gradually increased also. However, because alkyl mercury poisoning normally affects only the young, the adult Hucklebys, Ernest and Lois, escaped injury.

[4] The oldest Huckleby child, Dorothy Jean, has impaired speech, locomotion, sight and use of her hands. She has undergone rehabilitation, but the effects of the poisoning that she now manifests are permanent disabilities.

The son, Amos, is blind, his speech is greatly impaired, he walks with great uncertainty, and he cannot use his hands effecitvely. His disabilities are also permanent.

The other daughter, Ernestine, and the baby, Michael, are blind and neither can walk or talk. These conditions are permanent.

[5] The background of other litigation and further details about the controversy appear in *First National Bank in Albuquerque* v. *Nor-Am Agricultural Products, Inc.*, 537 P.2d 682 (N.M. Ct. App.).

claims of negligence were that the failure of PRD to require a label with an adequate warning of the danger of food-chain poisoning, and the failure to cancel the registration of Panogen 15 on the basis of known facts, were a proximate cause of the injuries; that the registration would have been cancelled had PRD followed an Interdepartmental Agreement among the Departments of Agriculture, Interior and HEW; and that the number of Public Health Service objections to PRD over the registration of products containing organic mercury compounds should have lead [*sic*] to testing and investigation on the adequacy of the labels.

The Government denied any negligence. It also alleged that PRD employees were exercising due care in the administration of the statute and regulations and hence it was exempt from liability under the exception in 28 U.S.C.A. § 2680(a), and that liability was likewise barred by the discretionary function exception of § 2680(a).

After a lengthy trial the district court found for the Government. The court's opinion essentially found that PRD had evaluated the label in accordance with FIFRA and the regulations as far as specific label items required by the statute and regulations were concerned; that PRD had discretion in that it must make policy judgments as to necessary label contents beyond those specific requirements; that the decision on the need for further testing and investigation of the alkyl mercury compound was a determination within the discretion of the Director of PRD; and that argument as to the failure of PRD to implement the Interdepartmental Agreement was immaterial because cancellation of Panogen's registration was within the Director's discretion.

The court concluded, *inter alia*, that where the agency performed its duties under the statute, and where the evaluation of the label and the decision to re-register the product involved discretion, even if that discretion was abused, 28 U.S.C.A. § 2680(a) applied and the Government was immune from suit. The action was dismissed and this appeal followed.

I

FEDERAL REGULATION OF PESTICIDES

FIFRA provides the basic framework for the federal regulation of "economic poisons" in interstate commerce.[6] The Act requires that every economic poison must be registered with the Secretary of Agriculture before it can be marketed in interstate commerce. 7 U.S.C.A. § 135b(a). In order to have his product registered under the Act, an applicant had

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[6] The Act defines an "economic poison" as follows, 7 U.S.C.A. § 135(a):

> (1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any insects, rodents, nematodes, fungi, weeds, and other forms of plant or animal life or viruses, except viruses on or in living man or other animals, which the Secretary shall declare to be a pest, and (2) any substance or mixture of substances intended for use as a plant regulator, defoliant, or dessicant.

A fungicide is an economic poison. See 7 U.S.C.A. § 135(a),(d). Throughout this opinion the terms "economic poison" and "pesticide" will be used interchangeably.

The first attempt at federal regulation of pesticides was the Insecticide Act of 1910 which prohibited the interstate sale of any insecticide or fungicide which was adulterated or misbranded within the meaning of the statute. 36 Stat. 331 (1910). This Act was repealed when FIFRA was enacted in 1947. 61 Stat. 163.

The passage of FIFRA added several important components to the federal scheme of pesticide regulation including controls over label language and the requirement that an economic poison be registered with the Secretary of Agriculture before it could be marketed in interstate commerce. *See* generally H. Rep. 313 (80th Cong., 1st Sess), 1947 U.S. Code & Cong. Serv. 1200-06. The Act was substantially strengthened by amendments in 1964. 78 Stat. 197; and *see* H. Rep. 1125 (88th Cong., 2d Sess.), 1964 U.S. Code Cong. & Admin. News 2166-67. Further amendments have occurred but they came after the period with which we are concerned.

to demonstrate to the satisfaction of the Secretary[7] that his economic poison is effective as claimed and that it meets the safety requirements of the Act. 7 U.S.C.A. § 135b(b).

The Secretary delegated his authority to the Director of PRD. 7 CFR § 362.3 (Jan. 1, 1970).[8] In order for a product to be registered, the manufacturer was required to submit to PRD an application for registration which included copies of the proposed labeling and the results of tests which measured the product's toxicity and efficacy. 7 U.S.C.A. § 135b(a); 7 CRF § 362.10(c) (Jan. 1, 1970). The application was evaluated by three separate groups within PRD. First, the "new chemicals evaluation staff" reviewed the label for accuracy in such areas as ingredient statements, chemical composition and chemical nomenclature. Second, the "product evaluation staff" reviewed the test data and the labels for the purpose of evaluating statements on the poison's effectiveness in the control of pests and other plant diseases. Third, the "pesticides safety evaluation staff" reviewed the toxicological data relating to the product's safety with respect to man and animals, and determined which warnings and precautionary statements should be placed on the label. When the poison's labeling was approved and the Secretary found that the claims for the product were warranted, he registered the product. 7 U.S.C.A. § 135b(b).

This registration was good for five years. At the end of this time the Secretary was authorized to cancel the registration, or, if requested by the applicant in accordance with the regulations, the pesticide could be re-registered for another five-year period. 7 U.S.C.A. 135b(f) (1976 Supp.). However, at any time when an economic poison's labeling was found not to comply with the Act, the Secretary could suspend or cancel the product's registration. 7 U.S.C.A. § 135b(c) (1976).

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[7]On December 2, 1970, the administration of FIFRA was transferred from the Secretary of Agriculture to the Administrator of the Environmental Protection Agency pursuant to Regoranization Plan No. 3 of 1970, 84 Stat. 2086.

[8]In citing the regulations we refer to those of the Department of Agriculture in effect at the pertinent time.

MERCURY, METHYLMERCURY AND PANOGEN 15[9]

Mercury is often combined with organic chemical compounds to form what are known as "organic mercurials." These serve a wide variety of purposes. In agriculture, it was discovered that organic mercurials were effective as fungicides and that methylmercury was one of the most effective. The first reported use of an organic mercurial as a seed treatment to kill plant fungi was reported in 1913. This practice became widespread in the United States and other developed parts of the world by the 1930s.

A typical mercury fungicide will contain both active and inert ingredients. The active ingredient is often a methylmercury combined with another chemical compound in such a way that the active ingredient is then water soluble. This facilitates the fungicide's application on seeds during the treatment process. For example, the only active ingredient in Panogen 15 is Cyano(methylmercuri)guanidine which is a combination of methylmercury and guanidine. This compound comprises 2.2% of the Panogen 15 by weight. The remainder (97.8%) is made up of inert ingredients.

Panogen 15 was first registered with the Department of Agriculture in 1953 and has been re-registered several times since then, most recently in 1968. Panogen's registration was suspended in January, 1970, primarily due to the Huckleby incident.[10]

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[9]The scientific data discussed in this part were developed by an expert witness of the plaintiffs and are not in dispute.

[10]*See Nor-Am Agricultural Products, Inc. v. Hardin*, 435 F.2d 1133, reversed on procedural grounds on rehearing *en banc*, 435 F. 2d 1151 (7th Cir.), cert. dismissed, 402 U.S. 935.

The Panogen 15 sold to the Golden West Seed Company came in 54-gallon drums. The drum label shown to have been in use at about the time of these injuries is reproduced in the appendix to this opinion.[11] The most pertinent parts of the label to note for our purposes are the following warnings under the caption "Caution":

> This product is toxic to fish and wildlife. Keep out of any body of water. Treated seeds exposed on soil surface will be hazardous to birds and other wildlife. Rinse equipment and containers and dispose of wastes by burying in non-crop lands away from water supplies.

Further down under the heading "Precautions" was a statement directed to persons using Panogen 15 to treat seeds. This statement referred to the contents of the tags to be placed on bags of treated seed, and it read in part:

> . . . The statement 'Do not use this seed for food, feed or oil purposes' must appear in 8 point or larger.[12]

The plaintiffs claim that these and other label components were insufficient to apprise Golden West of the possibility of food-chain poisoning, thus causing their injuries. The alleged negligence of PRD in approving Panogen's labeling is a primary part of the plantiffs' case.

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[11] The parties had some difficulty in locating the actual label on the 54-gallon drum sent to Golden West. However, the record supports the conclusion that the label in the appendix is an exact copy of the label that was placed on that drum. *See* VII R. 141 (Pl. Ex. 5); XVII R. 667; XVIII R. 933.

[12] The inclusion of this language on the label of treated seed was required by regulations issued under the Federal Seed Act. 7 U.S.C.A. § 1561 *et seq.*: *see* 7 CFR § 201.31a(d) (Jan. 1, 1970). The treated seed itself is not an economic poison within the meaning of FIFRA.

II

THE DISCRETIONARY FUNCTION EXCEPTION

The district court's ruling was based on 28 U.S.C.A. § 2680(a), which provides that:

§ 2680. Exceptions

The provisions of this chapter and section 1346(b) of this title shall not apply to–

(a) Any claim based upon an act or omission of an employee of the Government, exercising due care, in the execution of a statute or regulation, whether or not such statute or regulation be valid, *or based upon the exercise or performance or the failure to exercise or perform a discretionary function or duty on the part of a federal agency or an employee of the Government, whether or not the discretion involved be abused.* (Emphasis added).

The controlling issues on this appeal concern only the emphasized part of § 2680(a), the discretionary function exception. We go directly to these issues since the discretionary function exception is a jurisdictional bar, if it applies.*Cameron Smith v. United States*,_____ F.2d _____(10th Cir. 12/27/76).

In challenging the adverse ruling under § 2680(a), plaintiffs argue that PRD was not engaged in the exercise of a protected discretionary function in the evaluation and choice of warning and direction language for Panogen 15 labels; that FIFRA and the regulations do not contemplate that public policy judgments will be made by PRD regarding precautionary language; that the record shows that no risk-benefit judgment was made by PRD in such evaluation and choice of the label language; and that the district court erred in finding that PRD judgment on "necessary and if complied with adequate" labeling involved a policy making choice, this finding not being supported by the record. Further, plaintiffs contend that the omissions of PRD personnel in marshalling and submitting facts to the Secretary or his surrogate for consideration of cancellation or suspension of Panogen's registration were unprotected as discretionary functions. Plaintiffs' primary reliance is placed on *Griffin v. United States*, 500 F.2d 1059 (3rd Cir.).

Of course, *Dalehite v. United States*, 346 U.S. 15, is our main guide on the discretionary function question. In holding that the functions of Government personnel involved in the nitrate fertilizer program preceding the Texas City explosion were within the exception, the Court stated, *id.* at 35-36:

> It is unnecessary to define, apart from this case, precisely where discretion ends. It is enough to hold, as we do, that the 'discretionary function or duty' that cannot form a basis for suit under the Tort Claims Act includes more than the initiation of programs and activities. It also includes determinations made by executives or administrators in establishing plans, specifications or schedules of operations. Where there is room for policy judgment and decision there is discretion. It necessarily follows that acts of subordinates in carrying out the operations of government in accordance with official directions cannot be actionable.

Plaintiffs argue vigorously that *Griffin v. United States*, 500 F. 2d 1059 (3rd Cir.), calls for rejection of the Government's claim of immunity under § 2680(a). There the plaintiff alleged negligence in Government approval of a lot of Sabin oral polio vaccine which later proved to be substandard and produced severe injury. The Third Circuit held that the actions of HEW's Division of Biologic Standards in approving the lot of vaccine were in violation of agency regulations and that at issue was a scientific – but not policy making – determination as to whether each of the criteria listed in the regulation was met.[13] Thus the discretionary function exception was held not to apply.

We agree with the reasoning and the result in the *Griffin* case. However, in order to determine whether these principles call for rejection of the discretionary function argument in our case, we must focus on the requirements of the statute and the regulations involved here.

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[13]The court also held that in disregarding some factors specified by regulation, there was a violation of a nondiscretionary command in the regulations, placing the actions outside the exception. 500 F.2d at 1066-68.

There are portions of the requirements on labeling that are specific and mandatory. Here a Category I poison ("highly toxic to man") was involved and mandatory label elements included the skull and crossbones, the word "poison" prominently in red on a background of distinctly contrasting color, and a statement of an antidote for the economic poison. 7 U.S.C.A. § 135a(a) (3); 7 CFR § 362.116(b) (2) (Jan. 1, 1970). However, these parts of the labeling are not at issue on this appeal.[14]

Instead, plaintiffs' claims of negligence and omissions concern other labeling requirements not involving such specific, mandatory items. These other requirements as to warnings, precautionary language and "directions for use" were phrased in terms of general policy standards to be applied by the agency.[15] For example, 7 U.S.C.A. § 135(z)(2)(c) and (d) provided that an economic poison is "misbranded":

> (c) if the labeling accompanying it does not contain directions for use which are *necessary and if complied with adequate for the protection of the public;*
>
> (d) if the label does not contain a warning or caution statement which may be *necessary and if complied with adequate to prevent injury* to living man and other vertebrate animals, vegetation, and useful invertebrate animals; (Emphasis added).

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[14]There was a claim of alleged negligence asserted in the trial court pertaining to the antidote statement, but this is not argued on appeal.

[15]These standards were applied when Panogen's application for registration was submitted with the proposed labeling as required. *See* 7 U.S.C.A. § 135b(a)(3); 7 CFR § 362.10(c)(Jan. 1, 1970). *See* also the testimony of Dr. Cueto on the consideration of proposed labels and changes required to make them adequate. XVIII R. 932. Numerous changes requested and incorporated on the Panogen label during its 17 year registration are reflected in Defendant's Ex. A, the registration jacket.

In prescribing required warnings and caution statements for labels, the regulations also incorporated the same general standard, *i.e.*, that of statements "necessary and, if complied with, adequate to prevent injury . . ."[16]

Thus, the statute and the regulations staked out only generalized policy standards for the precautions, warnings and directions for use. To enforce these standards, and give content and meaning to them, the agency was required to make policy judgments in evaluating the adequancy of the labeling. *See*

[16] 7 CFR § 362.9 (Jan. 1, 1970) provided that:

> Warning or caution statements, which are *necessary and, if complied with, adequate to prevent injury to living man and useful vertebrate animals, useful vegetation, and useful invertebrate animals, must appear on the label* in a place sufficiently prominent to warn the user, and must state clearly and in non-technical language the particular hazard involved in the use of the economic poison, *e.g.*, ingestion, skin absorption, inhalation, flammability or explosion, and the precautions to be taken to avoid accident, injury, or damage. (Emphasis added).

Further 7 CFR § 362.116 (Jan. 1, 1970) provided:

> (a) *Requirements of the act.* Section 2.z. (2)(d) of the act provides that an economic poison is misbranded if its label does not contain a warning or caution statement which may be *necessary and if complied with adequate to prevent injury to living man and other vertebrate animals,* vegetation, and useful invertebrate animals. . .
>
> (c) *Miscellaneous Provisions.* (1) Warning or caution statements on the labels of economic poisons must give concise and easily understood warnings as to the hazards associated with the use of the products, together with instructions to be followed to measure adequate protection . . . (Emphasis added).

In particular, we note that in dealing with warnings and precautions for organic mercury compounds the regulations have a significant provision that "[d]ue to wide variation in characteristics *each product must be considered individually.*" 7 CFR § 362.16(d) *(Mercury Compounds)* (iii) (Jan. 1, 1970) (Emphasis added).

See also 7 CFR § 362.105(b)(5)(Jan. 1, 1970), pertaining to directions for use, which requires that the directions include:

> *Any other pertinent information which in the opinion of the Director is necessary for the protection of the public.* (Emphasis added).

Stearns Electric Paste Co. v. *EPA*, 461 F.2d 293, 310 (7th Cir.); *Continental Chemiste Corp.* v. *Ruckelshaus*, 461 F.2d 331, 336 (7th Cir.). We feel this is true as to all components of the labeling complained of by the plaintiffs – the warnings, precautions and directions for use. Thus this case is unlike *Griffin* where scientific measurement against given specific standards was involved – not a determination in general terms for the protection of the public safety.[17]

We recognize that the Federal Tort Claims Act waives the Government's immunity in sweeping language. *United States* v. *Yellow Cab Co.*, 340 U.S. 543, 547. Moreover, the exceptions to the waiver are to be narrowly construed. *See Dalehite, supra* at 31 & n. 24; *Cameron Smith* v. *United States, supra*, ___ F.2d ___, ___ (10th Cir. 12/27/76. We are admonished that in interpreting the exceptions, we should include only those circumstances within the words and reason of the exception. *Dalehite*, supra at 31.

We must hold here, however, that the functions on which the negligence claims are founded are within the words and reason of the exception. Evaluation of the labeling did involve scientific as well as public policy considerations, but it was not confined to a narrow scientific function such as evaluating the vaccine under specified criteria in the *Griffin* case. The examination of the labeling under such standards as that of "necessary and if complied with adequate for protection of the public . . ." called for a judgment in the discretionary area. *See Hendry* v. *United States*, 418 F.2d 774, 783 (2d Cir.); *Coastwise Packet Co.* v. *United States*, 277 F. Supp. 920 (D. Mass.), *aff'd* 398 F.2d 77 (1st Cir.), *cert. denied*, 393 U.S. 937. Therefore we must agree with the district court that the discretionary function exception applies.

[17] The Third Circuit's opinion pointed out that the DBS function was not to determine if the lots of vaccine were safe for release, but instead was the duty to ascertain if specific neurovirulence standards of the regulation had been met. *See* 500 F. 2d at 1066 n. 16A.

A further argument made by the plaintiffs is based on the testimony of Dr. Hays, Director of PRD from 1966 to 1970. This testimony was to the effect that risk-benefit analysis, which was utilized by the agency when it made decisions on registration and cancellation of economic poisons, was not used when considering the adequacy of labels. He agreed that the best warning and most adequate directions on labels would be required "regardless of toxicity or [the] risk-benefit ratio." XVIII R. 825-26. The plaintiffs say that the testimony shows that no discretionary function was exercised with respect to labeling requirements. We cannot agree. The fact that the highest standards would be observed in judging the adequacy of labels does not alter our view that the generalized requirements for labels "necessary and if complied with adequate for protection of the public," 7 U.S.C.A. § 135(z)(2)(c), necessitated the exercise of discretionary judgment.

Plaintiffs press one final argument which is unrelated to labeling but deals instead with the authority to suspend or cancel the product's registration. They contend that omissions of PRD personnel in failing to marshal and submit facts to the Secretary or his delegate for a decision on cancellation were not protected as discretionary functions. Plaintiffs say that there was nothing more than a *pro forma* compliance with the statute in 1968 when Panogen 15 was re-registered and thus no policy judgment was exercised at all.

We note first that the decision-making as to possible suspension or cancellation does implicate a policy choice based on substantive standards of product safety in terms of protection of the public and impact on living man. *See Continental Chemiste Corp.* v. *Ruckelshaus, supra,* 461 F.2d at 335-36. Whether such discretion is exercised and possibly abused, or whether there is a failure to exercise the discretion, such acts or omissions related to the cancellation function are within the terms of the exception provided by § 2680(a).

We feel the claims and proof relating to alleged failure to marshal and submit data to the Secretary or to his surrogate, the Director of PRD, fall in the same category.[18] These actions are an integral part of the process for any possible cancellation or suspension of a registration. If we accepted plaintiff's argument that such acts of negligence or such omissions of staff personnel are unprotected, then

> . . . the protection of § 2680(a) would fail at the time it would be needed, that is, when a subordinate performs or fails to perform a casual step, each action or nonaction being directed by the superior, exercising, perhaps abusing, discretion.

Dalehite, supra at 36.

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[18] Actually at trial the plaintiffs established through the testimony of the officials that the Director himself and his Assistant had knowledge of the facts about mercury dangers which are discussed by the plaintiffs in connection with this issue. Thus the argument in essence attacks the Director's failure to cancel or suspend the registration on the basis of these facts.

There is a related argument that there was further proof of negligence, unprotected by the discretionary function exception, in the failure of the Department of Agriculture to implement a "Memorandum of Agreement between Secretary of Agriculture, Secretary of the Interior, and Secretary of Health, Education and Welfare," 29 Fed. Reg. 5808 (May 1, 1964). The argument is that the Department of Agriculture failed to implement the agreement which called for exchange of information and conferences on pesticide problems. The district court did find that the agreement was never implemented with regard to Public Health Service objections to pesticides. Nevertheless, we agree with the court that the agreement did not modify the substantive provisions of FIFRA. The function of cancellation remained unchanged, and any omissions or negligence in exercising that function were protected by § 2680(a).

In sum, we must agree with the ruling of the district court.[19] As Judge Bratton concluded his opinion on this tragedy, he expressed these thoughts with which we are in full agreement and which we hope will move those who can do so to provide special relief:

> It is with regret that the issues in this case are resolved against the plaintiffs. The Huckleby tragedy is very painful to observe, and the damage to the Huckleby children defies adequate articulation. The additional burdens placed upon the family by the accident are so great that they compel the hope that private relief will be available to this stricken family through Congressional action.

AFFIRMED.

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[19] As was ordered as to costs in the trial court, the parties will bear their own costs on this appeal.

GENERAL INFORMATION

Panogen 15 is recommended for the control of diseases caused by organisms carried on the seed, such as: Seed-borne stinking smut or bunt of wheat, oat smut and seed-borne oat blight (Helminthosporium victoriae), covered smut, black loose smut and stripe of barley, stem and covered smut of rye, seed-borne root rots of cereals, scab of cereals (Fusarium blight), loose and covered kernel smut of sorghums, black leg of sugar beet, seedling blight of flax, seedling blight of rice, seed-borne diseases and seed decay of peanuts, seed-borne rust and Alternaria of safflower. It also reduces infection from surface seed-borne anthracnose and usually reduces seed decay and damping-off or sore-shin of cotton. Panogen 15 reduces seed decay and seedling blight of corn, soybeans, peas, and beans. Control of seed diseases and seedling blights will usually result in increased stands and yields.

CAUTION

This product is toxic to fish and wildlife. Keep out of any body of water. Treated seeds exposed on soil surface will be hazardous to birds and other wildlife. Rinse equipment and containers and dispose of wastes by burying in non-crop lands away from water supplies.

PRECAUTIONS

Wear goggles or face shield to protect eyes from splashing while handling fungicide.

Do not breathe fumes from treated seed or from disinfectant.

Do not apply this fungicide to seed indoors unless there is thorough ventilation.

Do not handle the fungicide or treated seed with bare hands. Wash off promptly with plenty of soap and water any fungicide that accumulates on the skin.

Do not eat or smoke while using this fungicide. Wash hands before eating or smoking.

Seed treated with Panogen 15 must be labeled as follows: "This seed treated with methylmercury dicyandiamide" in 8 point or larger. The actual rate of treatment must also be stated or the words "at the rate recommended by the manufacturer." The words "Poison Treated" must appear in type not less than ¼" in red on a white background and a skull and crossbones at least ½" must be shown. The statement "Do not use this seed for food, feed or oil purposes" must appear in 8 point or larger.

Treated seed should be stored in well-ventilated areas. Do not store near food or feed supplies. Do not use bags or other containers which have contained treated seed for packaging food or feed.

Keep container tightly closed except when removing contents. Store in a well-ventilated area.

Before discarding empty container wash thoroughly with water and detergent. Discard in a safe place.

Panogen 15 may be somewhat corrosive to aluminum, copper, zinc, or alloys of these metals. Do not permit solutions of Panogen 15 to remain in contact with these metals for extended periods of time.

THIS LABEL MUST NOT BE REMOVED OR RENDERED ILLEGIBLE.

553 **DO NOT RE-USE CONTAINER**

Panogen® 15

LIQUID SEED TREATMENT

READY TO USE FUNGICIDE

FOR WHEAT, OATS, BARLEY, COTTON, FLAX, SORGHUM, RICE, RYE, SUGAR BEETS, PEANUTS, SOYBEANS, SAFFLOWER, CORN, BEANS AND PEAS

U.S.D.A. Registration No. 2139-6

Active Ingredient: Cyano(methylmercuri)guanidine*	2.2%
(Mercury equivalent 1.5%)	
Inert Ingredients	97.8%
	100.0%

*Methylmercury dicyandiamide

POISON

DANGER

KEEP OUT OF THE REACH OF CHILDREN

This liquid is poisonous if inhaled, swallowed, or absorbed through skin. Do not breathe vapors. Do not get in eyes, on skin, or on clothing. Handle carefully. May produce delayed chemical burns.

ANTIDOTE:

Internal: If swallowed give milk or white of egg beaten with water, then a tablespoon of salt in a glass of warm water, and repeat until vomit fluid is clear. Repeat milk or white of egg beaten with water. CALL A PHYSICIAN IMMEDIATELY!

External: If spilled on skin, wash off immediately with large amounts of soap and water. If in eyes, flush with water for at least 15 minutes and get medical attention.

SEE LEFT PANEL FOR ADDITIONAL PRECAUTIONS.

Net Contents:

MORTON CHEMICAL COMPANY
DIVISION OF MORTON INTERNATIONAL, INC.
110 N. WACKER DRIVE · CHICAGO, ILLINOIS 60606

DIRECTIONS FOR USE

Seed should be cleaned and must be well cured before treatment.

Panogen 15 is delivered ready for use in any Panogen Seed Treater.

Panogen 15 can be used in other treaters designed to apply liquids at the appropriate dosage rates.

RECOMMENDED DOSAGES:

Wheat, oats, barley, rye, sorghum	½ fl. oz. per bu.
Cotton	
Acid delinted	2 fl. oz. per 100 lbs.
Machine delinted	3 fl. oz. per 100 lbs.
Fuzzy	4½ fl. oz. per 100 lbs.
Rice	½ fl. oz. per bu.
Flax	1½ fl. oz. per bu.
Beet seed (segmented)	4 fl. oz. per 100 lbs.
Peanuts	2¼ fl. oz./100 lbs.
Safflower*	1½-2 fl. oz./100 lbs.
Field corn, sweet corn	2-4 fl. oz./100 lbs.
Beans, peas, soybeans**	3-4 fl. oz./100 lbs.

*For best results treat at least 24 hours before seeding.

**Do not use Panogen 15 for treatment of Garbanzo beans.

For extended periods of storage in large bins, seed should be aerated.

IMPORTANT: READ BEFORE PURCHASE OR USE

Purchase or use of this product shall constitute acceptance of the following terms of sale. Morton Chemical Company (Morton) warrants that this product conforms to the chemical descriptions on this label and is reasonably fit for the purposes specified hereon. By way of limitation but not in derogation of the directions and statements printed on this label, Seller makes no warranty and no representation and Morton makes no further warranty or representation, expressed or implied, including but not limited to any warranty as to MERCHANTABILITY, and no agent of Morton is authorized to do so except in writing, with a specific reference to the foregoing warranty. Since neither Seller nor Morton has any control over the handling, storage, use or conditions of use of this product, Buyer or user assumes all risks and liability arising from handling, storage or use of this product under abnormal conditions or not in strict compliance with the directions and precautionary statements hereon. All claims related to the purchase, handling, storage or use of this product shall be barred unless written notice is given to Morton within 30 days after the loss is discovered. Liability of the Seller or Morton for any damages arising from a breach of this warranty shall be limited to exclude consequential commercial damages.

Product of U.S.A. Printed in U.S.A.

APPENDIX B

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW MEXICO

FIRST NATIONAL BANK IN ALBUQUERQUE as Guardian for and on behalf of DOROTHY JEAN HUCKLEBY, CHARLES AMOS HUCKLEBY, ERNESTINE HUCKLEBY and MICHAEL HUCKLEBY; DOROTHY JEAN HUCKLEBY; LOIS HUCKLEBY and ERNEST HUCKLEBY	)	
Plaintiffs,	)	
vs.	)	NO. 9705 CIVIL
UNITED STATES OF AMERICA,	)	
Defendant.	)	

MEMORANDUM OPINION

In this action, the plaintiffs seek damages from the defendant United States for negligence of its employees in the execution of the Federal Insecticide, Fungicide and Rodenticide Act [hereinafter F.I.F.R.A.], *7 U.S.C. § 135-135k*[1], and the regulations issued pursuant thereto at *7 C.F.R. § 362*[2].

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[1] In 1970, the functions of the Secretary of Agriculture and the Department of Agriculture under the Federal Insecticide, Fungicide, and Rodenticide Act were transferred to the Administrator of the Environmental Protection Agency.

[2] The regulations are now found at *40 C.F.R. § 162*, and all cites hereinafter will be to *40 C.F.R. § 162*.

The events that culminated in the filing of the suit began in August of 1969, when the plaintiff Ernest Huckleby and certain other hog-raisers were given a substantial amount of grain by the Golden West Seed Company in Clovis, New Mexico. The grain was hauled back to Alamogordo, New Mexico, where Mr. Huckleby and the others lived.

The men apparently had gone to the seed company upon information that they could get there cheap or free grain with which to feed their hogs. Mr. Huckleby raised hogs as a sideline to his regular work as a janitor in the Alamogordo Public Schools.

The grain which the men were given was old grain and, in part, was composed of the sweepings left on the floor of the seed company after completion of a treatment process during which liquid Panogen 15, a fungicide containing organic alkyl mercury, was applied to the seed.

In all, Mr. Huckleby made two trips to get such grain, and he ultimately had approximately one and one-half tons of it. Because part of the grain had gone through the Panogen 15 treatment process, it had scattered throughout seeds that were pink, the color deposited during the Panogen treatment. Some of the grain the men received was sacked, and some of it was loose, requiring that it be shoveled onto their trucks.

Mr. Huckleby took his share of the grain and stored it in a shed in the back yard of his home. From the shed he thereafter took amounts of the grain to his hog pens, where it was mixed with garbage he had collected while doing janitorial work at several public schools in Alamogordo. After the mixture was cooked, he or a member of his family fed it daily to the hogs.

In the first week of October, the Hucklebys slaughtered one of the hogs for family consumption and, after the meat had been dressed by a local butcher, began eating it at least once each day until the end of November, when the key to the freezer in which it was kept was lost.

In early December, the first of the Huckleby children became ill. By early January, two more children were ill, and state and federal authorities had been called in to determine whether an epidemic of some sort might be starting.

An investigation into the matter was launched, and by mid-January it was determined that the Huckleby children were suffering from organic mercury poisoning, contracted by having eaten the meat from the hog that had been fed the Panogen-treated grain.

Ultimately, four Huckleby children were to be so afflicted, for Mrs. Huckleby delivered in March of 1970 a baby boy who had contracted organic mercury poisoning during gestation. The alkyl mercury contained in the pork eaten by Mrs. Huckelby during pregnancy had crossed the placenta and gone into the system of the fetus.

Alkyl mercury is a highly toxic substance. Once ingested, it moves rapidly through the body and is not thrown off by the body. As the hog ate the small amounts of the grain daily, the mercury level built up in its body and remained there at the time it was slaughtered. When the Hucklebys began eating the meat from the hog, the level of alkyl mercury began building up in their bodies.

Because alkyl mercury poisoning normally affects only the young, the adult Hucklebys escaped damage to themselves. The young Hucklebys, however, suffered tremendous damage.

Alkyl mercury poisoning does irreversible damage to the central nervous system. It affects speech, locomotion, and the ability to grasp objects or otherwise use one's hands properly. It also causes blindness or impaired vision. It does not, however, shorten the life-span of one afflicted by it.

The oldest Huckleby child, Dorothy Jean, has impaired speech, locomotion, sight, and use of her hands. She has undergone rehabilitation, but the effects of the poisoning she now

manifests are permanent disabilities.

The son, Amos Huckleby, is blind as a result of the poisoning. His speech is greatly impaired, and he walks with great uncertainty. He cannot use his hands effectively. His disabilities are also permanent.

The daughter, Ernestine, and baby Michael are blind, and neither can walk or talk. These conditions are also permanent.

This action was filed pursuant to 28 U.S.C.A. §§ 2674, 1346(b), which authorize such suits against the United States.[3] The plaintiffs seek recovery from the defendant because the Panogen 15 coating the grain fed to the Huckleby livestock was registered by the Pesticide Regulation Division [hereinafter P.R.D.] of the Agricultural Research Service in the Department of Agriculture [hereinafter Agriculture], and its label was approved by the P.R.D. Specifically, the plaintiffs' claim that before and at the time of the accident the P.R.D. had sufficient knowledge of the toxic effects of alkyl mercury upon man and animals and of its casual introduction into the food chain through ingestion of it by animals so that the failure of P.R.D. to either require an adequate label or to cancel registration of the product was a proximate cause of the damage suffered by the Hucklebys. They also contend that, had the P.R.D. followed

[3]28 U.S.C.A. § 2674 provides in pertinent part:

The United States shall be liable, respecting the provisions of this title relating to tort claims, in the same manner and to the same extent as a private individual under like circumstances . . . .

28 U.S.C.A. § 1346(b) provides in pertinent part that:

[T]he district courts . . . shall have exclusive jurisdiction of civil actions on claims against the United States, for money damages . . . [for] personal injury . . . caused by the negligent or wrongful act or omission of any employee of the Government while acting within the scope of his employment, under circumstances where the United States, if a private person would be liable to the claimant in accordance with the law of the place where the act or omission occurred.

an Interdepartmental Agreement[4] between Agriculture, the Department of Interior [hereinafter Interior], and the Department of Health, Education, and Welfare [hereinafter H.E.W.], calling for consultation and establishing a procedure for resolving objections to the registration of a product, that Panogen's registration would have been cancelled. Last, the plaintiffs cite the lack of testing and investigation by the P.R.D. as a source of the damage they suffered. In this connection, they claim that the number of objections to the registration of the products containing organic mercury compounds filed with the P.R.D. by the Public Health Service [hereinafter P.H.S.] should have raised sufficient doubts to lead to testing and field investigation of the public understanding of the label warnings and directions on mercury compounds and of the risk of misuse of such products.

The Government asserts that the exemptions contained in the Federal Tort Claims Act[5] are applicable to this case. First, it is claimed, the acts or omissions complained of fall within the discretionary function exemption in Section 2680. In the

[4]The Interdepartmental Agreement, filed April 30, 1964, provided that each department undertake to keep the other departments fully informed of developments in knowledge on the safe use of pesticides. It also provided that Agriculture would furnish the other two departments a weekly listing of all proposals concerning registration or re-registration, while H.E.W. would similarly furnish a weekly listing of all proposals affecting tolerances. Each department had the right to object to any proposal, such objection to be supported by appropriate scientific data, and, in the event the departments could not agree upon a resolution, the matter was to be referred to the Secretary of the department charged with final action for decision.

[5]28 U.S.C.A. § 2680 provides in pertinent part that:

The provisions of this chapter and section 1346(b) of this title shall not apply to –

(a) Any claim based upon an act or omission of an employee of the Government, exercising due care, in the execution of a statute or regulation, whether or not such statute or regulation be valid, or based upon the exercise or performance or the failure to exercise or perform a discretionary function or duty on the part of a federal agency or an employee of the Government, whether or not the discretion involved be abused.

alternative, the claim is that the P.R.D. employees exercised due care in their effectuation of the statute and regulations. Third, the contention is advanced that what the Government did was in the performance of a uniquely governmental function and thus cannot form a basis for liability. Finally, the Government claims that proper resolution either of the issues of whose negligence actually got the product into the hands of the Hucklebys or contributory negligence releases it from liability.

During the period germane to this action, the P.R.D. was the agency within the Department of Agriculture responsible for effectuating the pesticide requirements of F.I.F.R.A., and to the director of the P.R.D. were delegated the Act's functions. In order for a product to be registered, the manufacturer of a pesticide had to submit to P.R.D. an application for registration or re-registration, together with copies of the label it proposed to use on the product. No pesticide could be shipped in interstate commerce unless it was registered with P.R.D. and was properly labeled, including label directions for use, precautions, and ingredients.

Depending upon its nature, the information supplied by a manufacturer was channeled to one of the staffs within the division. Each staff reviewed the information assigned to it to ascertain compliance with the Act and the regulations. Thus, for example, the safety evaluation staff would be assigned the task of determining whether the precautionary statement appearing on a manufacturer's proposed label adequately complied with the act and regulation. The manufacturer was apprised of any shortcomings, so that he could submit another label which corrected the problems existing in the label before the P.R.D. for review.

The label was forwarded to the director of P.R.D. for his approval after each staff had satisfied itself that the label bore the proper information.

Re-registration of a product entailed much the same procedure, and the file on that product was reviewed in the same manner as was an original request for registration.

The Secretary was given the power to refuse to register or re-register any product if it appeared to him that it or its label did not comply with F.I.F.R.A. The refusal was to follow notice of the problem to the applicant, who then had a chance to correct it and avoid the refusal to register or re-register.

Among the Act's provisions also was one that allowed the Secretary of Agriculture, in the event he should deem it necessary to protect the public from imminent hazard, to suspend immediately the registration of any product. It was under the authority of this provision that the registration of Panogen 15 was suspended shortly after the Huckleby accident.

The Interdepartmental Agreement referred to above was one of the results of the public furor about pesticides in the early part of the past decade. It involved Interior and H.E.W. in the registration procedure so that fish and wildlife could be protected and so that steps could be taken both to prevent economic poisons from entering the food chain and to seize any contaminated foodstuffs intended for the food chain. Accordingly, H.E.W.'s Food and Drug Administration [hereinafter F.D.A.] set the tolerance level on economic poisons entering the food chain, and its Public Health Service [hereinafter P.H.S.] undertook to review requested registrations and to object to the registration of any economic poison it believed should not be permitted on the market.

Under this scheme the F.D.A. set a zero tolerance on mercury compounds. The P.H.S. initially lodged with the P.R.D. an across-the-board objection to the registration or re-registration of any organic mercury compounds, but, by 1968, it was directing its objections to alkyl mercury compounds.

In 1966, the P.R.D. refused to allow any further organic mercury compounds or new use patterns for such compounds to be registered, but it permitted those compounds already registered to continue to be registered. This was not necessarily in response to P.H.S. objections. In fact, the agreement between the departments had not been implemented to any significant

degree at the time of the accident here in question. The P.R.D. resolved the P.H.S. mercury objections by re-registering mercury compounds, and the disagreement about this between the P.H.S. and it was never referred to the Secretary for his decision.

Panogen 15 was first registered by the P.R.D. in 1953, and its registration jacket showed the most recent P.R.D. review activity with regard to it, other than the suspension and cancellation procedures, to have been in 1968.

The Panogen 15 sold to and used by the Golden West Seed Company came in 54 gallon barrels. The label on each drum sold to the seed company, insofar as important to this action, was red and white, with the skull and crossbones, the words poison and danger, and the admonition to keep out of the reach of children appearing prominently on the front panel. Also on the front panel was the advice that the liquid was poisonous if inhaled, swallowed, or absorbed through the skin, together with the warning not to get it in the eyes, on the skin, or on the clothing. The antidote statement appeared immediately below this information. The antidote given if the liquid was swallowed was to give milk or white of eggs beaten with water and followed by a tablespoon of salt in a glass of warm water, repeating the procedure until after the vomiting so induced produced a clear fluid. Finally, the words "call a physician immediately" appeared in capital letters.

On the side panel of the label it cautioned that the product, including any treated seeds exposed on the soil surface, was toxic to fish and wildlife; that the produce [*sic*] should be kept out of any body of water, and that wastes should be buried in non-crop lands away from water supplies.

Among the precautions on the side panel were directions for labeling treated seed. The words "poison treated" and the skull and crossbones were to appear on the tags that went on bags of treated seed, as well as a statement not to use the seed for food, feed or oil purposes.

The gist of plaintiffs' misbranding argument is that the regulations and the statute were violated by the P.R.D., so that the discretionary function exemption is not applicable to this case. Their relevant claims are that Panogen 15 was misbranded in its label's directions for use, warning statements, and antidote statement, and in that when used in accordance with commonly recognized practice it was injurious to man.

Plaintiffs' concept is that the Golden West personnel could not tell from the label on the Panogen 15 drum that if seed treated with it were fed to domestic animals and thus introduced into the food chain that it would be not only highly harmful to the animals but also very damaging to the young people who would eat the meat of such animals or who would be damaged before birth from the mother's having eaten such meat.

F.I.F.R.A. prohibits the interstate shipment or sale of any economic poison which is misbranded. 7 U.S.C.A. § 135a. The statute and regulations state that an economic poison is misbranded if its label is false or misleading to the public in any particular. 7 U.S.C.A. § 135(2)(1); 40 C.F.R. § 162.14.

The plaintiffs rely on these provisions, as well as the provisions of the statute which deal with the other misbranding[6] they allege the P.R.D. permitted.

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[6] 7 U.S.C.A. § 135(2) provides in pertinent part that the term misbranded shall apply:

(1) to any economic poison or device if its labeling bears any statement, design, or graphic representation relative thereto or to its ingredients which is false or misleading in any particular;

(2) to any economic poison –

. . . .

(c) if the labeling accompanying it does not contain directions for use which are necessary and if complied with adequate for the protection of the public;

(d) if the label does not contain a warning or caution statement which may be necessary and if complied with adequate to prevent injury to living man and other vertebrate animals . . . .

(Fn. 6 continued to next page).

The statutory mandate concerning directions for use states that the directions must be necessary and if complied with adequate for the protection of the public[7]. The accompanying regulation interprets the language of the statute and details, as to those germane to this action, where and when directions are required on a label.[8]

(Fn. 6 continued):

. . . .

(f) if any word, statement, or other information required by or under authority of sections 135-135k of this title to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or graphic matter in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use; or

(g) if in the case of [a] . . . fungicide . . . when used as directed or in accordance with commonly recognized practice it shall be injurious to living man or other vertebrate animals . . . .

[7]Note 6, *supra.*

[8]40 C.F.R. § 162.105 provides in pertinent part:

(a) Requirements of the Act. The Act and the regulations require that every economic poison which is subject to their provisions must be properly labeled including directions for use which may be necessary and, if complied with, adequate to protect the public.

(b) Contents of directions. The extent of detailed information required in the directions for use will vary, depending upon the nature of the proposed use, general knowledge of the economic poison and its uses, and possible hazards involved . . . .

. . . .

(c) When directions are required. Directions for use are required whenever they are necessary for the protection of the public. The public includes all persons who may be affected by the handling, storage, or use of the economic poison . . . .

The statute and regulations also require a warning or caution statement which may be necessary and if complied with adequate to prevent injury to living man and other vertebrate animals[9].

The statute defines the term antidote as a practical immediate treatment in case of poisoning and includes first aid treatment. 7 U.S.C.A. § 135(r). The pertinent regulations provide that, for highly toxic products (such as Panogen 15), the antidote state-

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[9]Note 6, *supra.*

40 C.F.R. § 162.9 provides in pertinent part:

Warning or caution statements, which are necessary and, if complied with, adequate to prevent injury to living man and useful vertebrate animals, useful vegetation, and useful invertebrate animals, must appear on the label in a place sufficiently prominent to warn the user and must state clearly and in nontechnical language the particular hazard involved in the use of the economic poison, *e.g.*, ingestion, skin absorption, inhalation, flammability or explosion, and the precautions to be taken to avoid accident, injury, or damage.

(a) The label of every economic poison shall bear warnings or cautions which are necessary for the protection of the public, including the statement, "Keep out of reach of children," and a signal word such as "Danger," "Warning," or "Caution" as the Director may prescribe, on the front panel or that part of the label displayed under customary conditions of purchase: Provided, however, The Director may permit reasonable variations in the placement of that part of the required warnings and cautions other than the statement "Keep out of reach of children" and the required signal word, if in his opinion such variations would not be injurious to the public . . . .

(b) The label of every economic poison which is highly toxic to man as described in § 162.8 shall bear the word "Danger" along with the word "Poison" in red on a contrasting background in immediate proximity to the skull and crossbones and an antidote statement including directions to call a physician immediately, on the front panel or that part of the label displayed under customary conditions of purchase: Provided, however, The Director may permit reasonable variations in the placement of the antidote statement if some reference such as "See antidote statement on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

See also note 10, *infra.*

ment should include both the advice to call a physician immediately and emergency first aid instructions that require only materials which are readily available[10].

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[10]40 C.F.R. § 162.116 provides in pertinent part:

(a) Requirements of the act. Section 2. z. (2) (d) of the act provides that an economic poison is misbranded if its label does not contain a warning or caution statement which may be necessary and if complied with adequate to prevent injury to living man and other vertebrate animals, vegetation, and useful invertebrate animals. Section 3.a.(3) of the act requires that any economic poison which contains any substance or substances in quantities highly toxic to man must bear on the label the skull and crossbones, the word "Poison" (in red) on a contrasting background, and an antidote statement.

. . . .

(i) Highly toxic products are required by the act to be labeled with the skull and crossbones, the word "Poison" (in red) on a contrasting background, and an antidote statement. The antidote statement should include the sentence "Call A Physician Immediately." In addition, the label should carry the word "Warning" and instructions for handling to reduce chances of injury in use.

. . . .

(c) Miscellaneous provisions. (1) Warning or caution statements on the labels of economic poisons must give concise and easily understood warnings as to the hazards associated with the use of the products, together with instructions to be followed to insure adequate protection. Precautionary labeling should warn against the hazards associated with the formulation both as it is sold and as used by the customer, whether it is suitable for use directly or must be diluted or mixed prior to application.

. . . .

(2) The precautionary labeling detailed in this interpretation for specific economic poisons is directed primarily toward the avoidance of hazard to the persons handling or applying the economic poison and to persons or animals exposed to the economic poison incident to its handling or use. The manufacturer should recognize the possibility of injury of other types associated with the use of his product and the label should bear suitable directions for the avoidance of such injury.

. . . .

(3) In general, the presence on the label of either the skull and crossbones and the word "Poison" or the warning "May Be Fatal If Swallowed" will substitute for such precautionary statements as "Avoid contamination of food" and "Keep away from children and domestic animals."

. . . .

(5) Antidote statements must contain emergency first aid instructions suitable for use by a layman. In most cases they should require only materials which are readily available.

The government has contended that its duties under F.I.F.R.A. are confined to ascertaining that label language covers intended uses, not misuses, of a product, and that it is the duty of the manufacturer, not it, to undertake to label against misuse of its product. However, the government does have a duty to the general public under F.I.F.R.A. The issue is whether it performed its duty or that it otherwise is immune because of the exemptions of Section 2680(a).

If the statute or regulations were violated by the P.R.D., liability would attach, but it cannot be said that the P.R.D. was guilty of failing to follow them. Its evaluation of the Panogen 15 label was in accordance with their directives, as far as specifics were concerned. For example, the specific direction that a highly toxic substance have a label with the words warning and poison on it was followed, as were the specific directives regarding the antidote statement. Other than such specific directions, the statute and regulations leave evaluation of the adequacy of the label to the judgment of P.R.D. personnel. What is a necessary and adequate if complied with warning to prevent injury to man is not spelled out in the statute or regulations. The same is true of the other label language challenged by the plaintiffs.

There simply is not the same kind of regulation or behavior by government personnel in this case as there was in *Griffin v. United States*, 500 F.2d 1059 (3rd Cir. 1974), relied on by plaintiffs. In that case the regulation mandated that lots of polio vaccine were not to be approved for release by the Division of Biologic Standards of H.E.W. until they had been subjected to safety testing under five criteria enumerated in the regulation and scientifically evaluated according to those criteria. The Division went beyond the regulation and discounted the results of particular tests because of "biological variation," which was not provided for in the regulation, and released polio vaccine that exceeded the neurovirulence reference. In addition, the court in *Griffin* found that the judgment made was that of a professional measuring neurovirulence, not those of a policy maker, *i.e.*, only a scientific determination was involved.

In this case, there is no regulation similar to the one in *Griffin*. F.I.F.R.A. and its regulations call for the exercise of policy judgments. For example, the decisions as to what are necessary and adequate if complied with warnings call for more than a scientific determination. Thus, the operational level negligence alleged by plaintiffs has no application to the activities of P.R.D. personnel with regard to the Panogen 15 label.

Special note should be taken of the plaintiffs' reliance on the language of 7 U.S.C.A § 135(z)(2)(g), which states a fungicide is misbranded if, [illegible]n used in accordance with commonly recognized practice, [illegible] injurious to living man. Plaintiffs assert that the P.R.D. knew that small amounts of mercury-treated grain were being introduced into the food chain and that this amounted to a use in accordance with commonly recognized practice. The evidence does not support a finding that the practice was commonly recognized, *i.e.*, that such use was frequent, widespread, and accepted. *See Southern Nat. Mfg. Co., Inc. v. Environmental Protection Agency*, 470 F.2d 194, at 198-99 (8th Cir. 1972).

The real thrust of plaintiffs' case is that the product was so dangerous that no label could be devised that would make it safe to market it and that the P.R.D. knew this by the mid 1960s. They rely on the regulation providing for cancellation if, on the basis of information available at the time, it appears that the product's label does not comply with the act, and is not corrected so that it does comply.[11] Hence, no matter what the

[11] 40 C.F.R. § 162.10(j) provides:

> Continuance of registration. If a registrant desires to continue the registration in effect, he shall notify the Pesticides Regulation Division in writing and it shall be continued in effect under the same terms as the original registration: Provided, however, That if, on the basis of information available at the time, it appears that the product or its labeling fails to comply with the Act, the registrant shall be so notified and afforded the opportunity to make the necessary corrections. If the corrections are not made, registration will be cancelled as provided in section 4.c. of the Act.

label language was, the plaintiffs claim is that the product was misbranded, and its registration should have been cancelled. This argument pre-supposes that the directions, warnings, and so forth on the product's label have been complied with, yet the product remained unsafe to market. There is no evidence in this case of compliance with the language of the Panogen 15 label.

Further, the decision to re-register the product involved policy considerations. Having reviewed the label and judged it against the standards enunciated in F.I.F.R.A., it was decided that the product's usefulness to the agricultural community and to the public as the beneficiary of the increased production resulting from its use on planting seed required that it be registered. Certainly it was known in the P.R.D. that the compound was highly toxic, but such knowledge by itself did not, under F.I.F.R.A., justify cancellation or refusal to re-register. Many highly toxic products are useful for a given purpose, and, with appropriate labeling, their marketing is permitted. The issue whether to allow the marketing of a poisonous substance is a policy choice. *See Sterns Electric Paste Co. v. Environmental Protection Agency*, 461 F.2d 293, 308 (7th Cir. 1972).

F.I.F.R.A. was intended to protect the general public, including plaintiffs, as well as to insure that products put on the market performed in accordance with the claims made by their manufacturers and promoted the public good. Where, as here, the agency performed its duties under the statute and where the evaluation of the label and the decision to re-register the product involved discretion, even if that discretion was abused, the provisions of 28 U.S.C.A. § 2680(a) apply, and the United States is immune from suit. *Dalehite v. United States*, 346 U.S. 15 (1953).

What has been said above applies with equal force to the plaintiffs' argument that the P.R.D. should have undertaken a testing and investigation program after the P.H.S. objected to the registration or re-registration of products such as Panogen 15. The product had been registered since 1953. The Huckleby accident was admittedly the first documented case of food

chain mercury poisoning in the United States. Certainly scientific knowledge on the subject of organic mercury had grown, and the P.R.D. was aware of the body of data relevant to such compounds. Its decision to not register any new mercury compounds or new patterns of use for mercury compounds reflected this knowledge. The need for further testing and investigation of alkyl mercury compounds was a matter to be determined by the discretion of the director, and is within the exception of Section 2680(a). *Dalehite v. United States,* 346 U.S. 15, at 38.

Plaintiffs' argument that the breach of the Inter-departmental Agreement fixes liability against the United States must also fail. The agreement did not modify the substantative provisions of F.I.F.R.A. or its regulations. The decision whether to refuse registration or to cancel a product is left to the Secretary of Agriculture to determine. Plaintiffs argue that, had the P.H.S. objections to alkyl mercury compounds been referred to the Secretary, he would have cancelled the registration of Panogen 15. The agreement was never implemented with regard to these objections, and the position of the P.R.D. in this connection was not commendable. Nevertheless, it is speculation to assume that, had the matter been referred to him, the Secretary would have cancelled the registration of Panogen 15. That was a matter left to his discretion under F.I.F.R.A., and the agreement did not change this.

It had been argued that the government's suspension of and ultimate cancellation of the registration of Panogen 15 for violation of 7 U.S.C. § 135(z)(2)(c),(d), and (q), the misbranding sections, amount to an admission that the label was inadequate in those particulars. These actions, taken after the accident occured, are not proper proof of negligence on the part of the government.

The fact that the Huckleby accident involves misuse of the product deserves further comment. The evidence establishes that someone at Golden West told Mr. Huckleby the grain was poisoned. There were also found in the grain stored in his shed

tags bearing the information required by the precaution statement on the side panel of the Panogen 15 label, but, if Mr. Huckleby saw these tags, he paid no attention to them. Finally, the evidence further establishes that Mr. Huckleby believed that, even though the grain was poisoned, he could get by with feeding small amounts of it to his hogs if he mixed it with garbage and cooked it. F.I.F.R.A. was not intended to cover a situation where information it required to be on the label was either not read or, if read, was disregarded.

It is with regret that the issues in this case are resolved against the plaintiffs. The Huckleby tragedy is very painful to observe, and the damage to the Huckleby children defies adequate articulation. The additional burdens placed upon the family by the accident are so great that they compel the hope that private relief will be available to this stricken family through Congressional action.

A Judgment in favor of the defendant United States will be entered herein, together with this Memorandum Opinion containing the Court's findings of fact and conclusions of law.

UNITED STATES DISTRICT JUDGE

APPENDIX C

STATUTORY AND REGULATORY PROVISIONS INVOLVED

7 U.S.C.A. § 135 (1964):

"Definitions

For the purposes of sections 135 to 135k of this title –

* * * * *

(z) The term "misbranded" shall apply –

(1) to any economic poison or device if its labeling bears any statement, design, or graphic representation relative thereto or to its ingredients which is false or misleading in any particular;

(2) to any economic poison –

* * * * *

(c) if the labeling accompanying it does not contain directions for use which are necessary and if complied with adequate for the protection of the public;

(d) if the label does not contain a warning or caution statement which may be necessary and if complied with adequate to prevent injury to living man and other vertebrate animals, vegetation, and useful invertebrate animals;

* * * * *

(f) if any word, statement, or other information required by or under authority of sections 135 - 135k of this title to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or graphic matter in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use; or

(g) if in the case of an insecticide, nematocide, fungicide, or herbicide when used as directed or in accordance with commonly recognized practice it shall be injurious to living man or other vertebrate animals, or vegetation, except weeds, to which it is applied, or to the person applying such economic poison; or"

* * * * *

7 U.S.C.A. § 135a (1964):

"Prohibited acts

(a) It shall be unlawful for any person to distribute, sell, or offer for sale in any Territory or in the District of Columbia, or to ship or deliver for shipment from any State, Territory, or the District of Columbia, to any other State, Territory, or the District of Columbia, or to any foreign country, or to receive in any State, Territory, or the District of Columbia from any other State, Territory or the District of Columbia, or foreign country, and having so received, deliver or offer to deliver in the original unbroken package to any other person, any of the following:

(1) Any economic poison which has not been registered pursuant to the provisions of section 135b of this title, or any economic poison if any of the

claims made for it or any of the directions for its use differ in substance from the presentations made in connection with its registration, or if the composition of any economic poison differs from its composition as represented in connection with its registration: *Provided*, That in the discretion of the Secretary, a change in labeling or formula of an economic poison may be made within a registration period without requiring reregistration of the product.

* * * * *

(3) Any economic poison which contains any substance or substances in quantities highly toxic to man, determined as provided in section 135d of this title, unless the label shall bear, in addition to any other matter required by sections 135 - 135k of this title –

(a) the skull and crossbones;

(b) the word "poison" prominently (IN RED) on a background of distinctly contrasting color; and

(c) a statement of an antidote for the economic poison.

* * * * *

(5) Any economic poison which is adulterated or misbranded or any device which is misbranded."

* * * * *

7 U.S.C.A. § 135b (1964):

"Registration of economic poisons – General requirements: single economic poisons; supplement statements; filing and contents of statements

(a) Every economic poison which is distributed, sold or offered for sale in any Territory or the District of Columbia, or which is shipped or delivered for shipment for any State, Territory, or the District of Columbia to any other State, Territory, or the District of Columbia, or which is received from any foreign country shall be registered with the [Secretary]: . . . .

"Submission of formula; registration by [Secretary] upon compliance with requirements

(b) The [Secretary], whenever he deems it necessary for the effective administration of sections 135 to 135k of this title, may require the submission of the complete formula of the economic poison. If it appears to the [Secretary] that the composition of the article is such as to warrant the proposed claims for it and if the article and its labeling and other material required to be submitted comply with the requirements of section 135a of this title, he shall register it.

Notification of noncompliance with requirements; corrections; refusal, suspension or cancellation of registration by [Secretary], effective date of cancellation; advisory committee and procedures; objections; public hearings; [Secretary's] orders; consultation with other agencies; confidential information, public hazard suspension; orders reviewable; defense of registration

(c) If it does not appear to the [Secretary] that the article is such as to warrant the proposed claims for it or if the article and its labeling and other material required to be submitted do not comply with the provisions of sections 135 to 135k of this title, he shall notify the applicant for registration of the manner in which the article, labeling, or other material required to be submitted fail to comply with said sections so as to afford the applicant for registration an opportunity to make the corrections necessary.

If, upon receipt of such notice, the applicant for registration does not make the corrections, the [Secretary] shall refuse to register the article. The [Secretary], in accordance with the procedures specified herein, may suspend or cancel the registration of an economic poison whenever it does not appear that the article or its labeling or other material required to be submitted complies with the provisions of sections 135 to 135k of this title. Whenever the [Secretary] refuses registration of an economic poison or determines that registration of an economic poison should be canceled, he shall notify the applicant for registration or the registrant of his action and the reasons therefor. Whenever an application for registration is refused, the applicant, within thirty days after service of notice of such refusal, may file a petition requesting that the matter be referred to an advisory committee or file objections and request a public hearing in accordance with this section. A cancellation of registration shall be effective thirty days after service of the foregoing notice unless within such time the registrant (1) makes the necessary corrections; (2) files a petition requesting that the matter be referred to an advisory committee; or (3) files objections and requests a public hearing. . . .

* * * * *

Time of cancellation and continuance of registration

(f) The [Secretary] is authorized to cancel the registration of the economic poison at the end of a period of five years following the registration of such economic poison or at the end of any five-year period thereafter, unless the registrant, prior to the expiration of each such five-year period, requests in accordance with regulations issued by the [Secretary] that such registration be continued in effect.

As amended May 12, 1964, Pub.L. 88-305 §§ 3, 4, 78 Stat. 190, 192; 1970 Reorg. Plan No. 3 § 2(a)(8)(i), eff. Dec. 2, 1970, 35 F.R. 15623, 84 Stat. 2086."

28 U.S.C.A. § 2674 (1965):

"Liability of United States

The United States shall be liable, respecting the provisions of this title relating to tort claims, in the same manner and to the same extent as a private individual under like circumstances, but shall not be liable for interest prior to judgment or for punitive damages."

* * * * *

28 U.S.C.A. § 2680 (1965):

"Exceptions

The provisions of this chapter and section 1346(b) of this title shall not apply to—

(a) Any claim based upon an act or omission of an employee of the Government, exercising due care, in the execution of a statute or regulation, whether or not such statute or regulation be valid, or based upon the exercise or performance or the failure to exercise or perform a discretionary function or duty on the part of a federal agency or an employee of the Government, whether or not the discretion involved be abused."

* * * * *

40 C.F.R. § 162.9 (1974):

"Warning or caution statement.

Warning or caution statements, which are necessary and, if complied with, adequate to prevent injury to living

man and useful vertebrate animals, useful vegetation, and useful invertebrate animals, must appear on the label in a place sufficiently prominent to warn the user and must clearly and in nontechnical language the particular hazard involved in the use of the economic poison, i.g., ingestion, skin absorption, inhalation, flammability or explosion, and the precautions to be taken to avoid accident, injury, or damage."

* * * * *

"**Registration.**

(j) *Continuance of registration.* If a registrant desires to continue the registration in effect, he shall notify the Pesticides Regulation Division in writing and it shall be continued in effect under the same terms as the original registration: *Provided, however,* That if, on the basis of information available at the time, it appears that the product or its labeling fails to comply with the Act, the registrant shall be so notified and afforded the opportunity to make the necessary corrections. If the corrections are not made, registration will be cancelled as provided in Section 4.c of the Act."

40 C.F.R. § 162.14 (1974):

"**Misbranding.**

An economic poison or device is misbranded if the article or its labeling is false or misleading to the public in any particular.

(a) Examples of statements or representations in the labeling of an economic poison or device which render it misbranded are the following:

* * * * *

(9) A true statement used in such a way as to give a false or misleading impression to the purchaser."

* * * * *

40 C.F.R. § 162.105 (1974):

"**Interpretation of requirements with respect to directions for use.**

(a) *Requirements of the Act.* The Act and the regulations require that every economic poison which is subject to their provisions must be properly labeled including directions for use which may be necessary and, if complied with, adequate to protect the public.

(b) *Contents of directions.* The extent of detailed information required in the directions for use will vary, depending upon the nature of the proposed use, general knowledge of the economic poison and its uses, and possible hazards involved. In general, directions should include:

* * * * *

(4) Any necessary limitation or restriction such as the time required between application and harvest of food crops, warning against use on certain crops, animals, objects, or in certain areas; and

(5) Any other pertinent information which in the opinion of the Director is necessary for the protection of the public.

(c) *When directions are required.* Directions for use are required whenever they are necessary for the protection of the public. The public includes all persons who may be affected by the handling, storage, or use

of the economic poison. Directions for use are necessary in the labeling of all products which are sold for use as economic poisons with the following exceptions:

* * * * *

(e) *Adequacy and clarity of directions.*

(1) Directions for use must be stated in terms which can be easily read and understood by the average person likely to use the economic poison. Directions must be adequate when carefully followed, to protect the public from economic cheat and from personal injury or damage to property. This requires sufficient completeness to insure the proper use of the product so as to obtain the desired results in pest control without causing injury to man, beneficial animals, or beneficial plants. Directions need not be exhaustive in every case, since some of the common economic poisons are intended for use against a large number of pests. Frequently the methods of control in different parts of the country vary and they may vary in a single locality from year to year, depending on weather conditions. It would be manifestly impractical to include detailed directions for all uses on the labeling of many widely used economic poisons.

(2) The need for detailed directions for use will be greater on household or home garden products likely to be used by persons not well informed in the use of economic poisons than it will be in the case of products intended for large scale agricultural or commercial uses. The large scale user is more likely to be informed of the properties of economic poisons

and also to rely on local agricultural authorities for advice. The need for detailed directions is also greater in the case of new economic poisons, or those of unusual compositions than it is in the case of older, well-known materials.

(3) The following general considerations apply:

* * * * *

(iii) Directions for use of new or unusual economic poisons shall be given in full detail, since information or advice on the use of the product from other sources is not likely to be available."

* * * * *

40 C.F.R. § 162.116 (1974):

"Interpretation with respect to warning, caution, and antidote statements required to appear on labels of economic poisons.

* * * * *

(c) *Miscellaneous provisions.*

(1) Warning or caution statements on the labels of economic poisons must give concise and easily understood warnings as to the hazards associated with the use of the products, together with instructions to be followed to insure adequate protection. Precautionary labeling should warn against the hazards associated with the formulation both as it is sold and as used by the customer, whether it is suitable for use directly or must be diluted or mixed prior to application.

(2) The precautionary labeling detailed in this interpretation for specific economic poisons is directed primarily toward the avoidance of hazard to the persons handling or applying the economic poison and to persons or animals exposed to the economic poison incident to its handling or use. The manufacturer should recognize the possibility of injury of other types associated with the use of his product and the label should bear suitable directions for the avoidance of such injury. When an economic poison is intended for use on or around feed or food products and contamination with harmful residues may occur, the label should bear specific statements adequate to avoid danger of contaminating such feed or foodstuffs. For some formulations, the residues of which may be readily removed by washing or mechanical means without damage to the product, a statement such as "remove residues at harvest by – (stating an effective method of removal) –" will be accepted. For formulations whose residues cannot be readily removed or where the product would be damaged in the process of removal, but where the residues disappear progressively, directions such as "Do not apply within – (stating a period adequate to reduce residues to a safe level) – days of harvest" will be acceptable. For still other formulations whose residues cannot readily be removed without damage to the product and do not disappear within a reasonable time, a statement such as "Do not apply after edible parts begin to form" may be required. When directions for use of sprays in food handling establishments are otherwise acceptable, a statement such as "Cover or remove all exposed food, utensils, and containers before spraying" may be required. In order to avoid contamination of milk or meat, certain economic poisons must bear directions against application in dairy barns, to dairy animals, or

animals being finished for slaughter, or to forage crops to be used as feed for dairy animals or animals being finished for slaughter. Products which would be used in a manner likely to destroy beneficial insects should bear appropriate directions, such as proper timing of application to avoid destruction of pollinating insects. Products which might be injurious to fish and wildlife after extensive use or indiscriminate disposal of excess material or spray-tank washings, and which bear directions for widespread use in areas where contamination of waterways would be possible, should bear directions such as "To protect fish and wildlife, do not contaminate streams, lakes, or ponds with this material." Herbicides which might be used in a manner likely to cause injury to beneficial vegetation should carry directions warning against the danger of drifting of dusts, spray mists, or vapors from volatile ingredients.

* * * * *

(d) *Acceptable warning, caution and antidote statements for economic poisons containing specified ingredients.* The following subparagraphs set forth or indicate acceptable warning, caution and antidote statements for economic poisons containing the ingredients specified therein. The exact wording used in the suggested statements is not obligatory, although the substance of all such statements will be required, unless under special conditions of handling or use it is unnecessary. The manufacturer is obligated to use any added warning, caution or antidote statements which any special characteristics or uses of his formulation indicate to be necessary.

* * * * *

Mercury compounds – (i) Inorganic salts (except calomel) – 20% and above (based on that percentage of elemental mercury present).

o Poison o
x x

Antidote: Give milk or white of egg beaten with water, then a tablespoonful of salt in a glass of warm water and repeat until vomit fluid is clear. Repeat milk or white of egg beaten with water.

Call a Physician Immediately!

Warning: Do not breathe dust. Do not get in eyes, on skin, or on clothing. Wash thoroughly after handling.

(ii) *Inorganic salts – Below 20% (based on the percentage of elemental mercury present).*

Warning: May Be Fatal If Swallowed! Do not get in eyes, on skin, or on clothing. Wash thoroughly after handling.

(iii) *Organic salts.* Due to wide variation in characteristics each product must be considered individually. See also phenyl mercuric acetate."

* * * * *